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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,809	05/16/2006	Michael Horstmann	RO4243US (#90568)	5957
28672 7590 07/08/2009 D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114			EXAMINER ORWIG, KEVIN S	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 07/08/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,809	Applicant(s) HORSTMANN, MICHAEL	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/16/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-14 are currently pending. Claims 1-12 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 13 and 14 are withdrawn from consideration.

Election/Restrictions

Applicant's election of Group III (claims 1-12, drawn to a device wherein the active substance is selected from oligonucleotides or polynucleotides) in the reply filed on Apr. 15, 2009 is acknowledged. In response to applicant's election, Groups I, II, IV, V, VI, and VII are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants have elected Group III with traverse.

The traversal is on the ground(s) that 1) the specific kind of active substance to be delivered is not of significant importance 2) that the instant invention causes more tissue damage than related prior art devices and 3) that Cormier allegedly teaches away from the instant invention, and 4) that the instant invention has advantages over the prior art.

This traversal is not found to be persuasive for at least the following reasons. First, the examiner disagrees that the specific active substance is not significant to the patentability of the claims. However, if applicants wish to admit on the record that each of the recited alternatives is an obvious variant of the others, as implied by their

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argument, the examiner would be willing to consider withdrawal of the election requirement between Groups II-VII. Second, applicant's arguments regarding an alleged teaching away and various alleged advantages/features of the instant application (which are not recited in the claims) are insufficient to warrant withdrawal of the restriction requirement since they do not demonstrate a special technical feature that is shared by all the groups of claims. Unity of invention only exists if the claimed inventions form a single general inventive concept *that defines a special technical feature that defines a contribution over the prior art*. See MPEP § 1893.03(d) and PCT Rule 13.2. Such a special technical feature is clearly lacking in this case as set forth in the restriction requirement (and herein). As pointed out in the restriction requirement, Cormier teaches that barbed microprotrusions help adhere the transdermal delivery device to the skin (paragraphs [0009], [0039], [0043], and [0051]). One of ordinary skill in the art would readily have envisioned adding barbs to the microneedles of Gertsek's device to increase adherence of the device to the skin as taught by Cormier. Therefore, the claimed device lacks an inventive step and the Groups cannot share a special technical feature. Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided or were not provided in English.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by CORMIER (U.S. 2002/0128599; Published Sep. 12, 2002).

1. Cormier discloses a device for transdermal delivery of active agents (abstract). The device comprises a backing layer (paragraph [0045]) and an array of barbed microprotrusions (Figure 1). An active agent is coated onto the microprotrusions, thus forming a reservoir of active agent (title; abstract; paragraph [0001]; claim 1). Instant claim 1 further requires that the microprotrusions be "needle-shaped". It is noted that the term "needle-shaped" has not been defined in the instant specification, and thus has been interpreted expansively. The microprotrusions of Cormier are "needle-shaped" as far as required by the instant claims. For example, nothing in the claim (or specification) requires that the microprotrusions be cylindrical. Since the silhouette of a needle is flat

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and, by definition, would still be considered "needle-shaped" a non-cylindrical microprotrusion with a sharp point can be reasonably construed as "needle-shaped" as well. For that matter, any microprotrusion with a generally sharp point could be construed as "needle-shaped". Thus, Cormier teaches each element of claims 1 and 2.

Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by GONNELLI (U.S. 2004/0106904; Provisional filed Oct. 7, 2002).

2. Gonnelli discloses a microneedle device for the transport of drug molecule across tissue (title; abstract). Gonnelli teaches an embodiment wherein an array of hollow microneedles are attached to a housing containing drug in an internal reservoir, the device further comprising a backing layer (paragraph [0085]). Gonnelli teaches that the microneedles may comprise plugs having barbs to catch biological tissue (paragraph [0029]; Figures 4A and 4B; claim 10). The plugs on the microneedles may have a cone or arrowhead shape to form barbed ends for gripping biological tissue (paragraph [0070]; claim 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WANG (U.S. 2005/0137525; Provisional filed Jun. 4, 2003) in view of KINGSFORD (U.S. 2005/0118388; priority to Nov. 15, 1999).

Wang discloses rotating microneedle arrays that "drill" holes into a biological barrier such as skin. The holes can be of controlled depth and are suitable for administering drugs (abstract). Wang teaches that the microneedle arrays can be used for transdermal penetration by rotating the microneedles. The microneedle, and particularly the tip of the microneedle, can have various shapes, for example, blunt,

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sharp, beveled, serrated, conical and/or frustoconical. The rotating microneedle operates much like a drill bit and can have a spiral-shaped material disposed on the outside surface of the microneedle tip to facilitate the drilling motion (paragraphs [0006], [0089]; Figure 8D; claim 34). Wang teaches that the microneedles can be driven by pneumatic or hydraulic actuators (paragraph [0122]). Wang teaches the attachment of the microneedles to a reservoir (e.g. paragraphs [0036] and [0051]). Thus, Wang teaches each element of instant claim 1 except for the explicit teaching of a backing layer. However, it would be obvious to an artisan to provide the devices of Wang with a backing layer as is typical in the art, for example as taught by Kingsford to provide support for the device (abstract; paragraph [0004]; claims 19, 30, and 34). Thus, Wang and Kingsford render instant claims 1, 3, and 4 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1, 2, and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonnelli in view of GERTSEK (U.S. 6,656,147; Filed Jul. 17, 2000; cited in the Office Action dated Mar. 16, 2009) and CORMIER (U.S. 2002/0016562; Published Feb. 7, 2002; cited in the Office Action dated Mar. 16, 2009).

3. The teachings of Gonnelli are presented *supra*. Gonnelli teaches that the length of the microneedles can be selected based on the intended use of the device, but is preferably between 30 and 200 μm (paragraphs [0021] and [0061]). Gonnelli teaches the use of an optional adhesive (paragraphs [0028], [0034], [0043], and [0082]), but does not explicitly disclose a polymer adhesive.

4. Gertsek discloses a microneedle device for delivering a substance into the skin of a patient (abstract). Gertsek teaches that a bottom surface of the device housing can comprise a pressure sensitive adhesive, which can be a suitable adhesive known in the art such as those commonly used in adhesive bandages (col. 5, lines 6-9). The skilled artisan knows that polymeric adhesives (i.e. pressure-sensitive adhesive polymers) are commonly used in such applications.

5. Gonnelli does not teach the placement of active substances in the adhesive layer. However, such would be obvious to the skilled artisan. For example, Cormier discloses transdermal delivery devices comprising a plurality of microprotrusions for anchoring to the skin and delivery of active agents (abstract). Cormier teaches the use of adhesives, just as Gonnelli (and Gertsek), but further teaches that the adhesive may contain an active agent (paragraph [0072]). Thus, it would have been *prima facie*

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obvious to one of ordinary skill in the art at the time of the invention to include an active agent in the adhesive layer taught by Gonnelli, to provide a reservoir in close proximity to the sites of microneedle puncture. Both Gonnelli (paragraphs [0019]-[0022]) and Cormier (paragraphs [0079] and [0080]) teach the use of poly/oligonucleotide drugs and vaccines (paragraphs [0079] and [0080]). In light of these teachings, the skilled artisan would have a high expectation of success in using the devices of Gonnelli to deliver oligonucleotide active agents and/or vaccines. The combination of Gonnelli, Gertsek, and Cormier renders claims 1, 2, and 5-12 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

Claims 1-12 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with

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alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643